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Mentor Self-Cath® Closed System 510(k) Notification

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92

The assigned 510(k) number is: K003873

Contact Person: Donna A. Crawford
Director, Corporate Regulatory Affairs
Mentor Corporation
201 Mentor Drive
Santa Barbara, CA 93111

Telephone: 805-879-6304
FAX: 805-879-6015

Date Prepared: December 12, 2000

Device Name and Classification

Trade Name: Mentor Self-Cath® Closed System

Common Name: Closed Urethral Catheterization System

Classification Name: Urological Catheter and Accessories

Product Code: Unknown

Manufacturer

Mentor Minnesota
1601 West River Road North
Minneapolis, MN 55411

Device Description

The Mentor Self-Cath® Closed System is an extension of the existing Self-Cath® product line. The device is a modification of the Mentor Self-Cath® sterile catheter whereby the catheter is contained in a sterile bag for collection of urine. The Mentor Self-Cath® Closed System is intended for use in male or female patients needing bladder drainage as determined by their physician. More specifically it is intended for use where drainage of the bladder into a suitable receptacle such as a commode or bedpan is not feasible or practical.

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Substantial Equivalence Claim

Mentor Corporation believes the proposed Mentor Self Cath® Closed System urine collection product to be substantially equivalent in form and function to the Bard Touchless® Plus Pre-Lubricated Urethral Catheter Kit and the MMG/O'Neil® Sterile Field Urinary Intermittent Catheter.

Indications for Use

The Mentor Self-Cath® Closed Urethral Catheterization System is intended for use in male or female patients needing bladder drainage as determined by their physician. More specifically it is intended for use where drainage of the bladder into a suitable receptacle such as a commode or bedpan is not feasible or practical. The device can be used by either the patient, once appropriate training has taken place, or by a trained health care professional.

Summary of Testing

Mentor has performed full device biocompatibility testing. The Mentor Self-Cath Closed Urethral Catheterization System has passed all *In Vitro* (Ames Mutagenicity and Cytotoxicity) and *In Vivo* (USP Mouse Systemic, Sensitization and Vaginal Mucous Irritation) testing at NAmSA, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 9 2001

Ms. Donna A. Crawford
Director, Corporate Regulatory Affairs
Mentor Corporation
201 Mentor Drive
SANTA BARBARA CA 93111

Re: K003873
Mentor Self-Cath® Closed Urethral
Catheterization System
Dated: March 7, 2001
Received: March 8, 2001
Regulatory Class: II
21 CFR §876.5130/Procode: 78 FCM and KOD

Dear Ms. Crawford:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

Mentor Self-Cath® Closed System
510(k) Notification

510(k) Number (if known): K003873

Device Name: Mentor Self-Cath® Closed Urethral Catheterization System

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the Counter Use _____
(Per CFR 801.109)

(Optional Format 1-2-96)

David A. Lynn
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K003873